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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/805,122

03/20/2004

Andreas M. Papas

YH-AquaE

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09/11/2009

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

09/11/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

drpatent@comcast.net  
dj\_russell@comcast.net

<b>Office Action Summary</b>	<b>Application No.</b> 10/805,122	<b>Applicant(s)</b> PAPAS ET AL.	
	<b>Examiner</b> ERIC E. SILVERMAN	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-11, 14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-11 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' response filed 7/27/2009 was received; claims 6-11, 14, and 16-21 are pending, claims 16-21 are withdrawn, and claims 6-11 and 14 are treated on the merits in this action.

#### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6, 7, 8, 10, and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/29300 for reasons of record.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-11 and 14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,824,638 to Burnside in view of US 5,883,103 to Burnside, WO 99/29300 and Roy for reasons of record.

On page 5 of Applicants' most recent response, the WO reference is erroneously referred to as WO/29300. The correct document number for this reference is WO 33/29300. This discrepancy appears to be due to a typographical error.

#### ***Response to Arguments***

Applicants' argue that the anticipation rejection is improper because the composition "consists essentially of" the recited elements, and the "type of surfactants

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disclosed by Burnside and Misra" are not included in the recited ingredients. In response, the argument that the term "consisting essentially of" excludes the surfactants of the prior art was considered and rejected in the Office Action mailed 1/21/2009. Even if the surfactants of the prior art do irritate mucus membranes, avoiding irritation to mucus membranes, or making emulsions without surfactants, was never disclosed to be part of the novel nature of the invention. "Consisting essentially of" language excludes components that alter the fundamental nature of the invention, but not other components. Here, Applicants disclosure does not indicate that exclusion of surfactants is part of the novel or fundamental nature of the invention; indeed, the disclosure does not even discuss eliminating surfactants or avoiding irritation of mucus membranes. Lacking such disclosure, Applicants' cannot now argue that the elimination of surfactants is fundamental to the invention. In addition, it bears noting that Applicants' do not argue that the exclusion of all surfactants is fundamental to the invention, nor have Applicants identified any specific surfactant that allegedly must be excluded. Instead Applicants argue, generally, that the surfactants of the applied art cannot be added. For this argument to be persuasive, there would have to be support in the original disclosure for the notion that exclusion of surfactants (either all surfactants or specific surfactants) is part of the fundamental novel characteristics of the invention. The Examiner has been unable to find any such support, and Applicants have not alleged such support to be present.

Applicants argue that the obviousness rejection is improper both because the surfactants of the prior art are allegedly excluded from the claimed composition, and

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because the art does "not distinguish linoleic acid sufficiently from other hydrophobic/lipophilic agents to provide a motivation to one of skill in the art to utilize it in the absence of surfactant/detergent to form oil-in-water emulsions." The first comment was addressed above; the claims do not exclude surfactants. The second comment is not written clearly and is difficult to comprehend. To the best of the Examiner's understanding, Applicants' are arguing that while the prior art may suggest hydrophobic agents generally, any mention of linoleic acid in the prior art is not specific enough to suggest its use. In response, WO '300 exemplified Vitamin E TPGS and linoleic acid in Examples 1 and 2. It cannot be said that exemplified agents are not taught with sufficient specificity to suggest to the artisan to use those agents.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites "essential fatty acids." The specification does not make indicate, and the artisan would not know, which fatty acids are "essential," nor is there any indication what the fatty acids must be "essential" for. To the extent that the term "essential fatty acids" refers to those fatty acids that an organism needs for life and cannot produce but must obtain by feeding (similar to essential amino acids), the essential fatty acids will differ from organism to organism. Because there is no

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indication what organism is used to determine what fatty acids are "essential," the artisan would be not know what fatty acids are included in the claim.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/  
Primary Examiner, Art Unit 1618